Proposed Maximum Residue Limit PMRL2016-56

Clomazone

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of a new use on canola to the product label of Command 360 ME™, containing technical grade clomazone, is acceptable. The specific uses approved in Canada are detailed on the label of Command 360 ME™, *Pest Control Products Act* Registration Number 27827.

The evaluation of this clomazone application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for clomazone is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRL can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for clomazone, is as follows.

Table 1 Proposed Maximum Residue Limit for Clomazone

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Clomazone	2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone	0.05[2]	Rapeseeds (canola)

[1] ppm = parts per million
[2] MRL proposed at the limit of quantitation (LOQ) of the enforcement method.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

Currently, there are no American tolerances on canola for clomazone as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide, and there are no Codex MRLs[1] listed for clomazone in or on any commodity on the Codex Alimentarius Pesticide Residues in Food and Feed webpage.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for clomazone up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limit

Residue data for clomazone in canola were submitted to support the domestic use of Command 360 ME on canola.

Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for clomazone was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for canola.

Table A1 Summary of Field Trial and Processing Data Used to Support MRL

Commodity	Application Method/ Total Application Rate (g a.i./ha)[1]	Pre-harvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Canola seed	Pre-plant soil application/ 404-436	90-122	<0.02	<0.02	No quantifiable residues observed when treated at exaggerated rates
	Pre-plant soil application/ 2110	122			

[1] g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of clomazone. Residues of clomazone in/on canola commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.